



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/026,952	12/27/2001	Irina Nazarenko	0942.4980006/RWE/AGU	7365

26111 7590 10/02/2003

STERNE, KESSLER, GOLDSTEIN & FOX PLLC
1100 NEW YORK AVENUE, N.W.
WASHINGTON, DC 20005

EXAMINER

TUNG, JOYCE

ART UNIT	PAPER NUMBER
----------	--------------

1637

//

DATE MAILED: 10/02/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/026,952

Applicant(s)

Nazarenko et al.

Examiner

Joyce Tung

Art Unit

1637

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-74 is/are pending in the application.
- 4a) Of the above, claim(s) 1-8 and 12-74 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 9-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claims 1-74 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:

- ☐ Certified copies of the priority documents have been received.
- ☐ Certified copies of the priority documents have been received in Application No. _____.
- ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

Art Unit: 1637

DETAILED ACTION

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1, drawn to a composition comprising at least three oligonucleotides, classified in class 536, subclass 22.1.
 - II. Claims 2-3, drawn to a method involving using the oligonucleotide of claim 1 for quantification and detection of one or more nucleic acid, classified in class 435, subclass 91.2.
 - III. Claims 4-8, drawn to a method of synthesizing or amplifying one or more nucleic acid molecules involving modified oligonucleotide, classified in class 435, subclass 91.2.
 - IV. Claims 9-11, drawn to a composition comprising at least one oligonucleotide modified at or near the 3' terminal nucleotide, classified in class 536, subclass 22.1.
 - V. Claims 12-23, drawn to a method of amplifying nucleic acid by using primers with modified 3' terminal nucleotide, classified in class 435, subclass 91.2.
 - VI. Claims 24-26, 28, 38-39 and 41 drawn to a composition comprising a nucleotide analogue and the kit containing the nucleotide analogue, classified in class 536, subclass 22.1.

Art Unit: 1637

- VII. Claims 27 and 60, drawn to a method of making a composition by using one or more nucleotide analogues of claim 24, 42 or 51, classified in class 435, subclass 6.
- VIII. Claims 29-37 and 40, drawn to a method of quantification, detection and synthesizing nucleic acid molecules by using the nucleotide analogue, classified in class 435, subclass 91.2.
- IX. Claims 42-59, 61, and 72-74, drawn to an oligonucleotide which has the features as set forth in claim 42, classified in class 536, subclass 22.1.
- X. Claims 62-71, drawn to a method of quantification, detection and amplification of one or more nucleic acid, classified in class 435, subclass 91.2.

2. The inventions are distinct, each from the other because of the following reasons:

Inventions and are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the products groups are Group I, IV, VI and IX are drawn to an oligonucleotide which can be used in nucleic acid purification.

3. Inventions VII, and I, IV, VI and IX are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as

Art Unit: 1637

claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the products groups can be made by another different process since the process groups, Group VII does not specify specific steps with specific material.

4. Inventions I, IV, VI and IX are distinct because each group of the inventions has different features, for example, Group I is drawn to a composition comprising at least three oligonucleotide, Group IV is drawn to a composition comprising at least one oligonucleotide with the modification at 3' terminal, Group VI is drawn to a composition comprising nucleic acid analogues and Group IX is drawn to an oligonucleotide which has the features different from another group as set forth in claim 42.

5. Inventions II-III, V, VIII, and X are distinct, if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, these inventions II-III, V, VIII, and X have different modes of operation, different functions, or different effects since each group has different steps and uses different primers as set forth by the description in the claims.

6. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

7. During a telephone conversation with Mr Frank Cottingham on 9/15/2003 a provisional election was made with traverse to prosecute the invention of group IV, claims 9-11.

Art Unit: 1637

Affirmation of this election must be made by applicant in replying to this Office action.

Claims 1-8 and 12-74 are withdrawn from further consideration by the examiner, 37

CFR 1.142(b), as being drawn to a non-elected invention.

8. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

Drawings

9. The drawings are approved by draftsman.

Claim Rejections - 35 USC § 112

10. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

11. Claims 10-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Art Unit: 1637

- a. Claims 10-11 recite the limitation "said modified ribonucleotide" in claim 10. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

13. Claims 9-11 are rejected under 35 U.S.C. 102(e) as being anticipated by Dale (6440723, issued 8/27/2002).

Dale discloses an array having associated polymer sequences with modified structure and kits containing such array (See column 1, lines 61-66). The modified structure comprises modifications to the sugar moieties (e.g., 2'-substituted ribonucleotide monomer) (See column 5, lines 63-67 to column 6, line 1). The chemical modification of the oligonucleotide may be at 5' end or 3' end (See column 6, lines 32-45). One or more alkyl can be placed on either end of the oligonucleotide (See column 12, lines 65-67 to column 13, lines 1-2), for example, 2'-O-alkyl (See column 13, lines 11-15). The invention also includes a kit containing the array associated with modified polymer, polymerase and reverse transcriptase (See column 26, lines 9-29). Thus the teachings of Dale anticipate the limitations of claims 9-11.

Art Unit: 1637

14. U.S. patent NO. 6,130,038 and 6,576,218 are made of record as references of interests.

Summary

15. No claims are allowable.
16. Any inquiries concerning this communication or earlier communications from the examiner should be directed to Joyce Tung whose telephone number is (703) 305-7112. The examiner can normally be reached on Monday-Friday from 8:00 AM-4:30 PM.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached at (703) 308-1119 on Monday-Friday from 10:00 AM-6:00 PM.

Any inquiries of a general nature or relating to the status of this application should be directed to the Chemical/Matrix receptionist whose telephone number is (703) 308-0196.

17. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Art Unit 1637 via the PTO Fax Center located in Crystal Mall 1 using (703) 305-3014 or 308-4242. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989).

Joyce Tung

September 20, 2003


ETHAN WHISENANT
PRIMARY EXAMINER